State of California—Health and Human Services Agency
Department of Health Services

California Department of Health Services
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Director

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TO: General Acute Care Hospitals/Ambulatory Surgery Centers
Director/Manager Risk Management Program
Director/Manger, Infection Control Program
Medical Director, Infection Control Program
Director/Manager Safety Program
Director/Manager, Quality Assurance/Performance Improvement Program
Medical Director Quality Assurance/Performance Improvement Committee

FROM: California Department of Health Services
Licensing and Certification Program

SUBJECT: Immediate Assessment of Endoscope Reprocessing Procedures and Event Notification

Priority: High: For immediate distribution to all inpatient and outpatient departments and services responsible reprocessing endoscopes. For immediate distribution to all physicians who perform endoscopic procedures in their office practices.

Over the past 18 months eight healthcare facilities have reported situations involving inadequate reprocessing of flexible endoscopes. This has resulted in notifying and offering testing to over 5000 patients of a potential exposure to hepatitis B and C viruses, and, in some instances, human immunodeficiency virus (HIV). Five of these situations have occurred over the past six months and were discovered by observing reprocessing technicians during performance improvement reviews. Although these situations primarily involved endoscopes used in gastroenterology procedures, similar problems have been observed with bronchoscopes and cystoscopes. Although no illness has been identified during the investigation of these situations, when large numbers of patients are tested for bloodborne viruses it is not unusual to find previously unidentified infections, particularly hepatitis C. In these circumstances it is difficult to exclude the possibility that the infection might have resulted from endoscopy.

These situations were primarily due to human errors and included failure to:

- Recognize the presence of auxiliary channels (suction and air) in newly purchased equipment;
- Manually clean auxiliary channels prior to disinfection or sterilization;
- Record the concentration of the disinfectant daily or more frequently depending on the volume of procedures performed;
- Change the disinfectant according to manufacturer's recommendations or when the concentration falls below acceptable levels;
- Assure that automated endoscope reprocessor (AER) channel attachments were appropriate to the scope being reprocessed and were connected properly;
- Change water and other filters on AERs as specified by the manufacturer;
- Assure that the AER was functioning according to the manufacturer's specifications (i.e., there is no obstruction or valve failure to reduce or prevent the flow of the disinfectant through the endoscope channels);
- Educate and observe that reprocessing technicians consistently follow facility specific procedures;
- Develop, implement and periodically assess the competency of reprocessing technicians;

Notification processes are often made more difficult due to the fact that medical records may not include the identification of the specific endoscope used on the patient, nor is it common practice to identify which AER was used to disinfect a specific endoscope, particularly if the unit possesses more than one AER and/or has AERs from several manufacturers.

Any endoscope which has been inadequately reprocessed poses a risk of transmission of infection; notification of all patients who might be at risk is now recommended regardless of the magnitude of risk. The assessment of the risk of infection from inadequately reprocessed endoscopes and decisions for appropriate patient testing and/or postexposure prophylaxis are best addressed on a case-by-case basis.

The California Department of Health Services strongly recommends that, as soon as possible, all healthcare facilities performing endoscopic reprocessing procedures implement the following recommendations.

Guidelines Review and Procedures Development

- Review current endoscopy infection control recommendations and guidelines (see references below) and manufacturers' instructions;
- Survey all departments in which endoscopy is performed (e.g., outpatient settings, surgical clinics, and medical offices as applicable) to determine the type(s) of endoscopic procedures performed and the methods of endoscope reprocessing;
- Develop and implement new or revised endoscope cleaning, disinfecting or sterilizing procedures, if necessary; and
- Review Food and Drug Administration (FDA) advisories, manufacturer's alerts and the scientific literature for reports related to defective endoscopic equipment, accessories and AER reprocessing equipment.

Education and Inservice Training

- Provide staff physicians who perform endoscopic procedures in their offices with appropriate cleaning, disinfecting and, when applicable, sterilizing procedures;
- Develop and implement a training and education program for all staff responsible for endoscope reprocessing; and
- Develop competencies for cleaning, disinfecting or sterilizing each type of scope including accessories and ensure that staff are thoroughly knowledgeable about:
    - Manufacturer's cleaning, disinfecting and sterilizing recommendations for each specific endoscope and accessories used in the facility;
    - Instructions for proper use of cleaning (enzymatic) solutions;
    - Instructions for proper use of high level disinfecting solutions; and
    - Instructions for drying the instruments and proper storage.

Infection Control and Quality Assurance

- Assure that healthcare workers assisting with procedures or responsible for reprocessing endoscopes wear personal protective equipment;
- Discard used enzymatic cleaning solutions after each endoscope is cleaned;
- Review AER or other automatic reprocessor preventive maintenance procedures with biomedical engineering or service representatives and periodically visually assess that the AER is properly functioning (i.e., the valves and connectors are delivering the proper amount of disinfectant and rinse water);
- Review preventive maintenance logs periodically;
- Review disinfectant concentration logs for each AER used. These logs should include the: 1) date and time the test was performed each day; 2) test results of the concentration of the disinfectant (depending on the volume of endoscopes

reprocessed each day the concentration of the disinfectant in the reservoir may have to be tested several times each day); and 3) date the disinfectant was changed; and
- Discard the disinfectant at the end of its reuse life (which may be single-use), regardless of the minimal effective concentration.
- A disinfectant may be added to an AER (or basin, if manually disinfected) according to manufacturer's directions. However, the reuse life of the disinfectant should be determined by the first use/activation of the original solution; i.e., the practice of "topping off" of disinfectant does not extend its reuse life.

Documentation to Facilitate Future Inquiries

- Maintain a log that includes the: 1) name of the patient; 2) medical record number; 3) date of the procedure; 4) specific procedure(s) performed; 5) physician performing the procedure; 6) type of endoscope used; and 6) serial number of the endoscope; and
- Identify the specific AER used to reprocess each endoscope (if more than one AER is installed) and the reprocessing cycle used on each endoscope.

Reporting Endoscope Reprocessing Deficiencies

- Report all endoscope reprocessing deficiencies to California Department of Health Services Licensing and Certification District Office and local health department. Assistance in the assessment of the risk of infection and decisions for appropriate patient testing and/or postexposure prophylaxis is available.

Resources

Nelson D, Jarvis WR, Rutala WA, et al. SHEA Position Paper: Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. Infect Control Hosp Epidemiol 2003; 24: 532-7. Also available at: www.shea-online.org/Assets/files/position_papers/SHEA_endoscopes.pdf.
(Endorsed by the American Society for Gastrointestinal Endoscopy, the Society for Healthcare Epidemiology of America, the Joint Commission on Accreditation of Healthcare Organizations, the American College of Gastroenterology, the American Gastroenterological Association, the American Society of Colon and Rectal Surgeons, the Society of American Gastrointestinal Endoscopic Surgeons, the Society of Gastroenterology Nurses and Associates, the Association of Perioperative Registered Nurses, the Association for Professionals in Infection Control and Epidemiology, and the Federated Ambulatory Surgery Association.)

Alvarado CJ, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. Association for Professionals in Infection Control. Am J Infect Control 2000; 28: 138-55. Also available at: www.apic.org (under Practice Guidance – Guidelines).

U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC). FDA and CDC public health advisory: infection from endoscopes inadequately reprocessed by an automated endoscope reprocessing system. September 10, 1999. Available at: www.fda.gov/cdrh/safety/endoreprocess.html.

Should you have questions regarding this letter, please contact Jon Rosenberg, M.D., Department of Health Services, Division of Communicable Disease Control at (510)-540-3233 or by email at jrosenbe@dhs.ca.gov or Chris Cahill at (415) 456-3857 or by email at ccahill@dhs.ca.gov.

Sincerely,

Original Signed by
Ruth I. Jacobs for Diane L. Ford

Diane L. Ford, Chief,
Field Support Branch